

Application Number 10/698,216
Amendment responsive to Office Action mailed April 5, 2007

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REMARKS

This Amendment is responsive to the Office Action dated April 5, 2007. Applicant has amended claims 1, 9 and 22 and added claim 28. Claims 1-23 and 25-28 are pending.

Information Disclosure Statement

In the Office Action, the Examiner stated that "unless references have been cited by the examiner on form PTO-892, they have not been considered." This statement is inconsistent with the prosecution history of the current application. Specifically, Applicant submitted a list of references on PTO-1449 on October 31, 2003. This list of references includes each of the references cited in Applicant's specification. The Examiner indicated that she had reviewed each of the references included on the PTO-1449 submitted October 31, 2003 on a copy of the PTO-1449 submitted October 31, 2003 attached to the Office Action dated July 26, 2006.

In light of the above prosecution history, Applicant respectfully requests the Examiner clarify her statement with respect to the references cited in Applicant's specification.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected each of the pending claims under 35 USC 103(a) as being obvious to one of ordinary skill in the art at the time of Applicant's invention. Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 1-12

In the Office Action, the Examiner rejected claims 1-4, 6-9 and 12 under 35 U.S.C. 103(a) as being unpatentable over Silverman (US 6,251,063) in view of Bley (US 6,592,859). The Examiner also rejected claims 5 and 10 under 35 U.S.C. 103(a) as being unpatentable over Silverman (US 6,251,063) in view of Bley (US 6,592,859) as applied to claim 4 above, in view of Silverman et al. (US 6,358,197). The Examiner also rejected claims 9-12 under 35 U.S.C.

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103(a) as being unpatentable over Silverman et al. (US 6,358,197) in view of Sawhney (US 2001/0046518) and further in view of Bley (US 6,592,859).

With reference to independent claims 1 and 9, for example, the applied references lack any teaching that would have suggested a tubular instrument having a distal end and an opening at the distal end, and a bulking prosthesis having a bulking prosthesis width approximately equal to a width of the opening at the distal end of the tubular instrument. Support for the amendments to claims 1 and 9 may be found from, e.g., FIGS. 2 and 4 and the accompanying text of Applicant's specification as originally filed.

In contrast to independent claims 1 and 9 as amended, Silverman (US 6,251,063) discloses implants injected in a solution.¹ Because it discloses implants injected as a solution, Silverman (US 6,251,063) fails to disclose or suggest a bulking prosthesis having a bulking prosthesis width approximately equal to a width of the opening at the distal end of the tubular instrument.

Bley (US 6,592,859) also fails to disclose or suggest a bulking prosthesis having a bulking prosthesis width approximately equal to a width of the opening at the distal end of the tubular instrument. For example, as shown in FIG. 2 unswelled solid polymers 19 are clearly smaller than the inner diameter of hypodermic needle 15.² This conclusion is also supported by the fact that unswelled solid polymers 19 are dispersed in carrier liquid 21 for injection.³ Sawhney (US 2001/0046518) likewise fails to disclose or suggest a bulking prosthesis having a bulking prosthesis width approximately equal to a width of the opening at the distal end of the tubular instrument. In this manner, the applied references fail to disclose or suggest each of the features of independent claims 1 and 9.

Dependent claims 2-8 and 10-12 are allowable for at least the reasons independent claims 1 and 9 as amended are allowable. In light of the clear distinctions between the features recited in independent claims 1 and 9 as amended and the cited references, Applicant reserves comment with respect to dependent claims 2-8 and 10-12. Applicant respectfully requests the Examiner withdraw the rejections to claims 1-12.

¹ Silverman (US 6,251,063), column 26, lines 15-35.

² Bley (US 6,592,859), FIG. 2.

³ Bley (US 6,592,859), column 3, line 60 to column 4, line 14.

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Claims 13-17

The Examiner rejected claims 13-15 under 35 U.S.C. 102(b) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Johnson et al. (US 6,338,345). The Examiner also rejected claim 16 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,338,345) as applied to claim 13, in view of Capeocchi et al. (US 5,489,300). The Examiner also rejected claim 17 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,338,345) as applied to claim 13, in view of Silverman (US 6,251,063).

With respect to independent claim 13, Johnson et al. (US 6,338,345) clearly fails to disclose a bulking prosthesis in the shape of a partial cylinder having an inner radius as claimed. For at least this reason, the Examiner's rejection of claims 13-15 is in error because the cited reference fails to disclose each and every feature of the claimed invention as required for a proper rejection under 35 U.S.C. 102(b). Applicant respectfully requests withdrawal of this rejection.

With respect to the rejection of independent claim 13 under 35 U.S.C. 103(a), the Examiner specifically stated that the bulking devices as disclosed by Johnson et al. (US 6,338,345) may be formed in a variety of shapes and sizes including a cylindrical, toric or rod shape, wherein the optimal dimensions are patient specific. The Examiner further stated that Johnson et al. (US 6,338,345) fails to disclose that the bulking prosthesis may be implanted around or within the anus of a patient, but failed to give weight to such a feature as recited in claim 13 as being direct to an intended use.

Applicant respectfully disagrees with the Examiner's analysis with respect to claim 13 on a variety of points. First, while Johnson et al. (US 6,338,345) does provide a list of various shapes for bulking device 16,⁴ none of these shapes is equivalent to a partial cylinder having an inner radius as claimed. Furthermore, Johnson et al. (US 6,338,345) fails to provide any teaching that would have lead one of ordinary skill in the art to produce a bulking device in the shape a partial cylinder having an inner radius as claimed. The mere suggestion that various shapes can be used is not specific enough to have rendered the specific configuration of Applicant's claimed bulking device obvious to a person of ordinary skill in the art.

⁴ Johnson et al. (US 6,338,345), column 6, lines 50-51.

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Second, the disclosure of Johnson et al. (US 6,338,345) is directed to an esophageal bulking device,⁵ and does not suggest using such a device in an anus of a patient. While Applicant does not agree that such claim language is merely intended use, as stated by the Examiner, because the limitations of claim 13 in question provide structural limitations. For example, claim 13 recites that the inner radius of the partial cylinder is sized to conform to close the anus. Thus, the dimensions of a device disclosed or suggested by Johnson et al. (US 6,338,345) must meet this structural limitation. In the current rejection, the Examiner has failed to provide any evidence that the bulking devices disclosed by Johnson et al. (US 6,338,345) are sized to conform to close the anus of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the anus of the patient and when the patient exercises voluntary control over an external sphincter, as recited in claim 13. In this manner, the current rejection clearly fails to account for each and every structural limitation recited in independent claim 13.

Dependent claims 14-17 are allowable for at least the reasons independent claim 13 is allowable. In light of the clear distinctions between the features recited in independent claim 13 and the bulking devices disclosed by Johnson et al. (US 6,338,345), Applicant reserves further comment with respect to dependent claims 14-17. Applicant respectfully requests the Examiner withdraw the rejections to claims 13-17.

Claims 18-21

The Examiner rejected claims 18, 19 and 21 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,338,345) in view of Silvestrini (US 5,824,086). The Examiner also rejected claim 20 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,338,345) and Silvestrini (US 5,824,086) as applied to claim 18, in view of Tu et al. (US 2002/0188308).

In the rejection of independent claim 18, the Examiner stated that Johnson et al. (US 6,338,345) fails to teach a bulking prosthesis has a sharpened tip as recited in independent claim 18. Applicant agrees with this statement. The Examiner further stated, however, that it would

⁵ Johnson et al. (US 6,338,345), Abstract.

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have been obvious to include a conical sharpened tip as disclosed by Silvestrini (US 5,824,086) with an esophageal bulking device as disclosed by Johnson et al. (US 6,338,345).

Applicant respectfully disagrees that a person of ordinary skill in the art would have considered obvious the Examiner's proposed modification of an esophageal bulking device as disclosed by Johnson et al. (US 6,338,345) to include a conical sharpened tip as disclosed by Silvestrini (US 5,824,086). Such modification is directly contradictory to the explicit teachings of Johnson et al. (US 6,338,345). For example, Johnson et al. (US 6,338,345) teaches at column 8, lines 13-17, "[T]he configuration of the bulking device 16 (e.g. sharp edges, etc.) operates in cooperation with the softness of the construction materials to optimize the compatibility of the bulking device. A smooth, blunt atraumatic outer surface is preferred."⁶ As taught by Johnson et al. (US 6,338,345), a conical sharpened tip would limit the compatibility of the esophageal bulking device as disclosed by Johnson et al. (US 6,338,345).

For at least this reason, one of ordinary skill in the art would not seek to modify the esophageal bulking device as disclosed by Johnson et al. (US 6,338,345) to include a conical sharpened tip as disclosed by Silvestrini (US 5,824,086). In this manner, the combined disclosures of Johnson et al. (US 6,338,345) and Silvestrini (US 5,824,086) would not have made the Applicant's claimed invention as recited in claim 18 obvious to one of ordinary skill in the art.

Dependent claims 19-21 are allowable for at least the reasons independent claim 18 is allowable. In light of the clear differences between the features recited in independent claim 18 and the applied references, Applicant reserves further comment with respect to dependent claims 19-21. Applicant respectfully requests the Examiner withdraw the rejections to claims 18-21.

Claims 22 and 23

The Examiner rejected claim 22 under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (US 2002/0188308) in view of Lat et al. (US 5,751,104). The Examiner also rejected claim 23 under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (US 2002/0188308) and Lat et al. (US 5,751,104) as applied to claim 22 above, in view of Culpen et al. (US 5,542,799).

⁶ Emphasis added.

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In the rejection of claim 22, the Examiner argued that Tu et al. (US 2002/0188308) discloses a bulking prosthesis comprising a sharpened tip and helical thread around the rod-like bulking prosthesis (as seen in Figures 32-34). However, Tu et al. (US 2002/0188308) fails to disclose a bulking prosthesis. Instead, Tu et al. (US 2002/0188308) discloses glaucoma stent devices.⁷ To further distinguish Applicant's invention from the disclosure of Tu et al. (US 2002/0188308), Applicant has amended claim 22 to specify that the bulking prosthesis assumes an enlarged state in the presence of water. Tu et al. (US 2002/0188308) and Lat et al. (US 5,751,104) clearly fail to disclose or suggest such a feature.

In this manner, the combined disclosures of Tu et al. (US 2002/0188308) and Lat et al. (US 5,751,104) would not have made the Applicant's claimed invention, as recited in claim 22 as amended, obvious to one of ordinary skill in the art.

Dependent claim 23 is allowable for at least the reasons independent claim 22 is allowable as Culpen et al. (US 5,542,799) also fails to disclose a bulking prosthesis that assumes an enlarged state in the presence of water. In light of the clear differences between the features recited in independent claim 22 and the applied references, Applicant reserves comment with respect to dependent claim 23. Applicant respectfully requests the Examiner withdraw the rejections to claims 22 and 23.

Claims 25-27

The Examiner rejected claims 25 and 26 under 35 U.S.C. 103(a) as being unpatentable over the combination of Johnson et al. (US 6,338,345) and Silvestrini (US 5,824,086) as applied to claim 18 above, in view of Silverman (US 6,251,063). The Examiner also rejected claims 25-27 under 35 U.S.C. 103(a) as being unpatentable over Wilk (US 2002/0091295) in view of Yeung et al. (WO 02/032321).

As discussed with respect to claim 18, the Examiner's proposed modification of an esophageal bulking device as disclosed by Johnson et al. (US 6,338,345) to include a conical sharpened tip as disclosed by Silvestrini (US 5,824,086) is directly contradictory to the explicit teachings of Johnson et al. (US 6,338,345). The same analysis applies to the subject matter of claim 25 in that the esophageal bulking device as disclosed by Johnson et al. (US 6,338,345)

⁷ Tu et al. (US 2002/0188308), paragraphs [0156]-[0165].

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would not have been modified by one of ordinary skill in the art to include a conical sharpened tip as disclosed by Silvestrini (US 5,824,086).

Furthermore, the Examiner has provided no argument as to why one of skill in the art would find it obvious to implant either a esophageal bulking device as disclosed by Johnson et al. (US 6,338,345) or a corneal insert as disclosed by Silvestrini (US 5,824,086) proximate to an anal sphincter as recited by claim 18, other than to point out that Silverman (US 6,251,063) generally discloses forming implants 371 in an anal sphincter.⁸ Implants 371 are not equivalent to a rod-like bulking prosthesis as recited in claim 25. Furthermore, the Examiner has provided no evidence as to why one of ordinary skill in the art would consider replacing implants 371 with a rod-like bulking prosthesis as claimed. Simply, Silverman (US 6,251,063), without modification, already teaches the treatment of fecal incontinence, and the combined disclosures of the cited references provide no reason one of ordinary skill in the art would seek to modify implants 371 of Silverman (US 6,251,063) to provide each of the features recited in claim 25.

With respect to the rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Wilk (US 2002/0091295) in view of Yeung et al. (WO 02/032321), these cites references also fail to disclose or suggest numerous features recited in the claim.

For example, while claim 25 recites implanting a rod-like bulking prosthesis proximate to an anal sphincter, Wilk (US 2002/0091295) instead teaches implanting magnetic elements in the wall of a bowel to close a hole in the bowel.⁹ Importantly, this hole is not an anal sphincter as claimed. Furthermore, Wilk (US 2002/0091295) teaches the use of the magnetic attractive forces of the implants to accomplish the closure of the hole. In this manner, one of skill in the art would not seek to modify the magnetic implants as disclosed by Wilk (US 2002/0091295) because the magnetic attractive forces of the magnetic implants are a necessary feature of the techniques disclosed by Wilk (US 2002/0091295).¹⁰

One of skill in the art would not find the magnetic elements of Wilk (US 2002/0091295) to be interchangeable with a swellable closure device as disclosed by Yeung et al. (WO 02/032321) as the swellable closure device does not provide magnetic attractive forces. Further, the swellable closure device disclosed by Yeung et al. (WO 02/032321) is not suggested as being

⁸ Silverman (US 6,251,063), column 28, lines 43-58.

⁹ Wilk (US 2002/0091295), paragraph [0056] and FIGS. 12A-12D.

¹⁰ Wilk (US 2002/0091295), abstract.

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suitable for implantation proximate to an anal sphincter, but is instead described as being implanted within urethral tissue.¹¹

Dependent claims 26 and 27 are allowable for at least the reasons independent claim 25 is allowable. In light of the clear differences between the features recited in independent claim 25 and the applied references, Applicant reserves comment with respect to dependent claims 26 and 27. Applicant respectfully requests the Examiner withdraw the rejections to claims 25-27.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-23 and 25-27 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claim

Applicant has added claim 28 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. No new matter has been added by new claim 28.

¹¹ Yeung et al. (WO 02/032321), page 11, lines 12-16.

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CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Although Applicant's remarks have focused on certain claims and claim limitations, Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserves the right to further address such rejections and/or characterizations.

No fees are believed to be due at this time. Please charge any additional fees or credit any overpayments to deposit account number 50-1778.

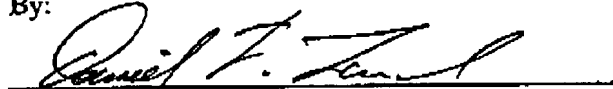
The Examiner is invited to telephone the below-signed attorney to discuss this application.

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